OCT 16 2006

510(k) Summary

This 510(K) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21CFR § 807.92

The assigned 510(K) number is:	K052907
Submitted by:	Michael Patton 6300 Bridgepoint Parkway Bldg. 2, Ste. 420 Austin, Texas, 78730 Phone: 512 329 0469 Fax: 512 328 9113 Email: mpatton@pattonsurgical.com
Date Prepared:	October 13, 2006
Establishment Registration Number:	Patton Surgical is located at 6300 Bridgepoint Parkway, Bldg. 2, Suite 420 in Austin, Texas 78730. We are registered with the Food and Drug Administration as Establishment Number 1651380.
Classification Name:	Electrosurgical, Cutting and Coagulation and Accessories
Common/Usual Name:	Anti-sticking solution
Proprietary Name:	PolarCoat
Indication for Use:	Patton Surgical PolarCoat is a single patient use device which is intended for use on electrodes to reduce sticking.
Device Description:	The Candidate Device is a yellow-brown substance, Lecithin with soy protein removed. The Candidate Device is a single patient device, available on sponge or in bottle, to be used on electrodes to reduce sticking. The Candidate Device is sterilized by the Irradiation method and packaged individually within a shipper container of 20 units per container.
Substantial Equivalence Claim:	The principles of operation and technology in the candidate device are similar to other devices such as the Mectra Labs, Inc.'s Electro-Lube, which the FDA has found to be substantially equivalent to preamendment devices as outlined below:

Product:	Electro-Lube
Manufacturer:	Mectra Labs, Inc.
510(K) Number:	K033880
Substantial Equivalence Date:	3/10/04

-End of summary-

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2006

Patton Surgical, Corp.
% Ms. Vikki Ballesteros
6300 Bridgepoint Parkway
Building Two, Suite 420
Austin, Texas 78730

Re: K052907
Trade/Device Name: PolarCoat
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: October 3, 2006
Received: October 6, 2006

Dear Ms. Ballesteros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Patton Surgical
PolarCoat, K052907
510(k) Notification

510(K) Number:	K052907
Device Name:	PolarCoat
Indications for Use:	Patton Surgical PolarCoat is a single patient use device which is intended for use on electrodes to reduce sticking.
Intended Use:	Patton Surgical PolarCoat is a single patient use device which is intended for use on electrodes to reduce sticking.

Prescription Use x
(Per 21 CFR 801Subpart D)

Over-the-Counter
(Per 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brennan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052907

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